REMARKS

Claims 1-9 were previously cancelled; Claims 10-18 were previously added; and new Claims 19 and 20 are presently added. Accordingly, Claims 10-20 are pending.

Rejection under 35 U.S.C. 102(e) (U.S.P.N. 6,028,099)

Claims 10-17 have been rejected as being anticipated by U.S. Patent No. 6,028,099 ("the '099 patent") in view of the Cole Eye Institute article. (See Office Action page 2, paragraph 3.)

Independent Claim 10 recites methods of treating ocular disorders by administering an octreotide. The ocular disorders recited are retinal edema, macular edema, age related macular degeneration and central serous chorio-retinopathy. Independent Claim 14 recites methods of treating macular edema by *topically* administering a somatostatin analog in the form of an ophthalmic liquid preparation.

In contrast, the '099 patent discloses treating choroidal neovascularization (CNV) with the administration of an inhibitor of the protein tyrosine kinase pathway. (See col. 2, lines 15-18.) The Examiner points to the section of the patent which lists "various compounds that can be co-administered" with the inhibitor. Within this extensive list of compounds, the somatostatin analog SMS 201-995 is enumerated. (See col. 9, lines 14-24.)

The '099 patent was filed on March 13, 1998 and issued on February 22, 2000. The parent application of the present continuation application is U.S. Serial No. 09/258,240, filed on February 26, 1999. Thus, the parent application was filed before the '099 patent issued.

Accompanying this amendment is a declaration pursuant to 37 C.F.R. §1.131 which establishes that conception of the present invention was achieved *prior to* the filing date of the '099 patent. Accordingly, the '099 patent is **not** available as a reference against the

present invention. (Please note the declaration is unexecuted. An executed declaration will be filed shortly.) One of the inventors, Dr. Kuijpers, is the declarant.

In particular, as can be seen in the declaration at paragraphs 3 and 4, Dr. Kuijpers treated a patient suffering from an ocular disorder associated with CNV with a somatostatin analog on October 16, 1996. As can be seen in the declaration at paragraphs 5 and 6, subsequent to October 16, 1996, there was a continuous diligence in reducing the invention to practice.

Since the present invention antedates the '099 patent, the '099 patent cannot be cited as a prior art reference. Accordingly the anticipation rejection is obviated.

Rejection under 35 U.S.C. § 112, first paragraph

Claim 18 recites a method of topically treating diabetic retinopathy with the administration of an octreotide in the form of an ophthalmic liquid preparation. Claim 18 has been rejected as *not* providing enablement for treatment of diabetic retinopathy topically. (See Office Action page 3, 1st and 2nd paragraphs.)

In particular, the Examiner states that "[t]he specification provides no working [*sic*] demonstrating topical eye administration works in treating diabetic retinopathy." The Examiner cites U.S. Patent No. 6,669,950 ("the '950 patent) as teaching that "periocular administration of drugs to treat macular degeneration or other posterior eye ailments usually results in the drug being quickly washed out and depleted from the eye via periocular vasculature and soft tissue, into the general circulation." (See Office Action page 3, 2nd paragraph.)

According to M.P.E.P. § 2164.04:

A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in

> describing and defining the subject matter sought to be patented **must be taken as being in compliance with the enablement requirement** of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. (Emphasis added.)

The instant specification teaches and describes the subject matter of Claim 18, *i.e.*, the treatment of diabetic retinopathy by the topical administration of octreotide. Thus, Claim 18 complies with the enablement requirement. Also, contrary to the Examiner's statement, working examples are not necessary to comply with the enablement requirement. (See M.PE.P. § 2164.02.)

It appears that the Examiner cites the '950 patent to show that "there is a reason to doubt the objective truth of the statements ... relied on for enabling support." However, Applicants respectfully assert that the Examiner has misrepresented the '950 patent. The '950 patent speaks only about disadvantages of periocular injections of a specific drug type, *i.e.*, angiogenesis inhibitors, not about periocular injections of all drug types. The patent does not speak of periocular injections in general. (See col. 1, lines 52-55, of the '950 patent.) It is improper to expand the teaching of the '950 patent to drugs other than angiogenesis inhibitors. In particular, the '950 patent does not teach anything about octreotide.

Moreover, contrary to the Examiner's assertion, topical compositions have been successfully used to treat posterior eye ailments, *e.g.*, glaucoma. (Note that the '950 patent lists glaucoma as a posterior eye ailment at col. 1, line 23.) By way of example, Exhibits 1-5 are attached. These exhibits are articles and a package insert demonstrating the use of several topically applied drugs to treat glaucoma. The exhibits include: Hayasaka *et al.*, "Effects of Topical Antiglaucoma Eye Drops on Prostaglandin E2-Induced Aqueous Flare Elevation in Pigmented Rabbits" *Investigative Ophthalmology & Visual Science 43(4)*:1142-1145 (April 2002); Emi *et al.*, "The Change of Ocular Blood Flow after Topical Instillation of Unoprostone Eye Drops, www.mcmaster.ca/inabis98/nemeth/emi0140/two. html (1998); "Glaucoma," *Drug Digest*, www.drugdigest.org/DD/PrintablePages/HealthConditions/1,20041,550106,00.html (December 2003); *Doctor's Guide to Medical and Other News*

"FDA Approves Cosopt Combination Eye Drops," www.pslgroup.com/dg/ 6B946.htm (April 8, 1998); and Xalatan® Eye Drops Package Insert, home.intekom.com/pharm/pharmaca/ xalatan.html (February 2005). Thus, Applicants have provided evidence to demonstrate that drugs applied topically are used to treat posterior eye ailments thereby successfully rebutting the Examiner's assertion.

Since the subject matter of Claim 18 complies with 35 U.S.C. 112, first paragraph, Applicants respectfully request withdrawal of the enablement rejection.

Obvious Type Double Patenting Rejection under 35 U.S.C. §101

The examiner has also provisionally rejected the Claims 10-17 under the judicially created doctrine of obvious type double patenting in view of copending Application Serial No. 09/519,647. (See Office Action page 3, paragraph 7.)

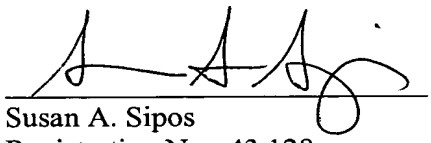
Application Serial No. 09/519,647 has not yet been allowed. Once such application is allowed, Applicants will consider filing a terminal disclaimer which would ensure that the patent term of any patent that may issue from the present application would not extend beyond the term of any patent issued from Application Serial No. 09/519,647.

New Claims

New Claim 19 recites a concentration range of the octreotide of 100 μg to 10 mg per day. Support for this claim is on page 9, lines 28-30. New Claim 20 recites the same subject matter as Claim 10, but uses "consisting essentially of " language. No new matter has been added.

Applicants respectfully submit that the application, including Claims 10-20, is now in condition for allowance, which action is earnestly solicited. If resolution of any remaining issue is required prior to allowance of this application, it is respectfully requested that the Examiner contact Applicants' undersigned attorney at the telephone number provided below.

Respectfully submitted,



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